## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

# (19) World Intellectual Property Organization

International Bureau



(43) International Publication Date 21 April 2005 (21.04.2005)

**PCT** 

## (10) International Publication Number WO 2005/034911 A1

(51) International Patent Classification7: 9/10, 9/12, 31/165, 31/56

A61K 9/00,

(21) International Application Number:

PCT/IB2004/003481

(22) International Filing Date: 8 October 2004 (08.10.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

0323684.1

9 October 2003 (09.10.2003)

(71) Applicant (for all designated States except US): JAGOTEC AG [CH/CH]; Eptingerstrasse 51, CH-4132 Muttenz (CH).

(72) Inventor; and

(75) Inventor/Applicant (for US only): MUELLER-WALZ, Rudi [DE/DE]; Hans-Vetter-Strasse 108, D-79650 Schopfheim (DE).

(74) Agents: BASSIL, Nicholas, Charles et al.; Kilburn & Strode, 20 Red Lion Street, London WC1R 4PJ (GB).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Burasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

### Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

AEROSOL FORMULATIONS COMPRISING FORMOTEROL FUMARATE DIHYDRATE, A PROPEL-LANT, ETHANOL AND OPTIONALLY A STEROID, WHERE THE FORMOTEROL FUMARATE DIHYDRATE HAS A WATER CONTENT OF 4.8-4.28% BY WEIGHT

(57) Abstract: A pharmaceutical aerosol formulation comprising formoterol fumarate di-hydrate in suspension, and a steroid in suspension, and a propellant, ethanol, and optionally a surfactant, wherein the formoterol furnarate di-hydrate has a water content of about 4.8 to 4.28 % by weight.